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RESPONSE UNDER 37 C.F.R. § 1.116 #21
EXPEDITED PROCEDURE - EXAMINING GROUP 1630 BP

PATENT 65-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Tongtong Wang et al.
Application No. : 09/519,642
Filed : March 6, 2000
For : COMPOSITIONS AND METHODS FOR THERAPY
AND DIAGNOSIS OF LUNG CANCER

Examiner : Michael L. Borin, Ph.D.
Art Unit : 1631
Docket No. : 210121.478C4
Date : May 27, 2003

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Commissioner for Patents:

In response to the Final Office Action dated November 25, 2002, please extend the period of time for response three months, to expire on May 25, 2003. Enclosed are a Petition for an Extension of Time and the requisite fee. Please amend the application as follows:

Remarks/Arguments begin on page 2 of this paper.

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REMARKS

Applicants submit this Reply in response to the Final Office Action dated November 25, 2002. Applicants note that this response is filed as a submission accompanying a Request for Continued Examination. Claims 61, 62, 65, and 66 are currently pending. Favorable reconsideration of the subject application is respectfully requested in view of the remarks provided herein.

Statement Regarding Third Supplemental Information Disclosure Statement

Applicants note that Form PTO-1449 associated with the Third Supplemental IDS filed July 18, 2002 contained a typographical error. Specifically, reference AK is incorrectly listed as Genseq Accession Number AAC1055, when it should be listed as Genseq Accession Number AAC10552. Applicants respectfully submit that this error has no substantive bearing upon the case, since copies of the sequence of Genseq Accession Number AAC10552 and European Patent Application Number EP 1033401 A2, which contains the same sequence, were provided to and have been initialed by the Examiner.

Rejection Under 35 U.S.C. §§ 101 and 112, First Paragraph

Claims 61, 62, 65, and 66 stand rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the alleged basis that the claimed invention lacks a patentable utility. The Action alleges that the claims are not supported by a substantial utility, and that the specification does not support the assertion that polypeptides of SEQ ID NO:786 may be used for cancer diagnosis or treatment. More specifically, the Action alleges that the specification fails to provide evidence that polypeptides of SEQ ID NO:786 are overexpressed in lung tumor cells. Although the Action acknowledges that it is reasonable to expect that a polypeptide is overexpressed when its encoding mRNA is overexpressed, the Action alleges that the specification does not demonstrate that the polynucleotide of SEQ ID NO:69, which encodes the polypeptide of SEQ ID NO:786, is overexpressed.

Applicants respectfully traverse this basis of rejection and submit that polypeptides of SEQ ID NO:786 possesses both specific and substantial utility, *e.g.*, in the detection of lung cancer. Furthermore, Applicants submit that one of ordinary skill in the art

would readily appreciate the usefulness of the claimed polypeptides for the detection of lung cancer, based upon the experimental results set forth in the instant specification.

Applicants submit that the specification as filed clearly demonstrates that polynucleotides of SEQ ID NO:69 are overexpressed in lung tumor tissue. Applicants respectfully request that the Examiner reconsider the evidence provided in Example 1 on page 70, line 26, through page 71, line 24, in its entirety. This section of Example 1 describes the process by which the polynucleotide of SEQ ID NO:69 was identified as being overexpressed in lung cancer. Specifically, this section of Example 1 describes microarray analysis of the mRNA expression levels of numerous clones isolated by subtractive hybridization from lung tumor tissue. Seventy-three of these clones were identified as being overexpressed in lung tumor as compared to normal lung tissue. These overexpressed clones were then sequenced, and their sequences were compared to known sequences in the EMBL GenBank databases. Applicants note that the example clearly indicates that the described sequence analysis was only performed on the clones that were overexpressed in lung tumor tissue. Accordingly, the fact that sequence analysis was performed on SEQ ID NO:69 indicates that the polynucleotide of SEQ ID NO:69 was overexpressed in lung tumor tissue as compared to normal lung tissue. As further evidence in support of the specification's demonstration that polynucleotides of SEQ ID NO:69 are overexpressed in lung tumor tissue, Applicants submit the accompanying Declaration of Dr. Tongtong Wang, which clarifies the results of the microarray experiments showing that polynucleotides of SEQ ID NO: 69 are overexpressed in lung tumor tissue. Since polynucleotides of SEQ ID NO:69 are overexpressed in lung tumor tissue, there is a reasonable expectation that their encoded polypeptides of SEQ ID NO:786 are also overexpressed in lung tumor tissue, as acknowledged by the Examiner. Accordingly, Applicants submit that these polypeptides possess patentable utility, *e.g.*, in the detection of lung cancer, and respectfully request that this basis of rejection be withdrawn.

Applicants wish to clarify any confusion resulting from their reference to polypeptides of both SEQ ID NOs:786 and 791 as L552S proteins by explaining that the initial screens for polynucleotides and polypeptides overexpressed in lung tumor tissue identified multiple forms of L552S polynucleotides and polypeptides, including SEQ ID NOs:786 and 791, all of which are referred to generally as L552S.

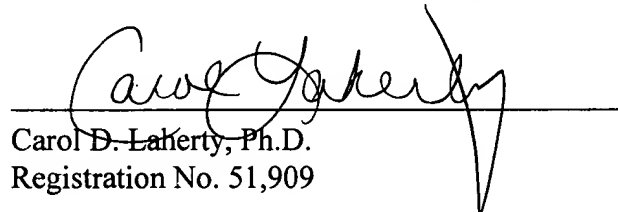
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants' attorney wishes to express her willingness to engage in a telephone interview to further the status of this application if any further concerns need to be addressed.

Respectfully submitted,

Tongtong Wang et al.

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CDL:sd

Enclosure:

Postcard
Petition for Extension of Time
Check
Request for Continued Examination (+ copy)

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